

**VALLEYLAB
FORCE ARGON™ II ARGON ENHANCED
ELECTROSURGICAL SYSTEM
SUMMARY OF SAFETY AND EFFECTIVENESS**

I. Product Description:

The Force Argon™ II Argon Enhanced Electrosurgical System is designed to provide a controlled flow of argon (an inert, non-reactive gas) to custom designed electrosurgical handsets powered by Valleylab electrosurgical generators. The handsets allows the surgeon to perform argon enhanced electrosurgery in open and laparoscopic procedures. Depending on the handpiece, the system can function in the following argon enhanced modes:

- Argon Shrouded Cut - Argon gas is delivered through the handset while the attached electrosurgical generator is activated in the cut mode.
- Argon Enhanced Coag - Argon gas is delivered through the handset while the generator is activated in the coag mode.

The Force Argon™ II Argon Enhanced Electrosurgical System has two gas flow modes; one for laparoscopic procedures (Low Flow Mode, 0.5 - 4.0 SLPM) and one for open procedures (Standard Flow Mode, 0.5-12 SLPM).

In addition, the system monitors the peritoneal pressure during laparoscopic procedures. The physician can set the desired pressure on the Force Argon™ II Argon Enhanced Electrosurgical System. When the peritoneal pressure approaches a predefined percentage of the set pressure, an alarm is activated to alert the user. A second alarm sounds when the actual peritoneal pressure reaches the set point. The physician can then vent the peritoneal cavity to relieve the pressure. The Force Argon™ Argon Enhanced Electrosurgical System is designed to allow the physician to continue to use argon enhanced electrosurgery when the peritoneal pressure set limit is reached.

The Force Argon™ II unit is designed to fit on a table top or a cart. Tank holders will be offered for use with the Valleylab Gas Delivery System carts which will accommodate argon tank sizes ranging from 14 to 42 cubic feet.

II. Intended Use

The Force Argon™ II Argon Enhanced Electrosurgical System is intended for use in both open, laparoscopic, and thoracoscopic surgical procedures (general, neurosurgical, gynecologic) where monopolar electrosurgery (cutting and

coagulation) is normally used. The Force Argon™ II Argon Enhanced Electrosurgical System provides a controlled flow of argon to electrosurgical handsets during cutting and coagulation. When the handset is activated in the gas enhanced modes, an argon gas plasma is created between the electrode and the tissue.

III. Safety and Performance Data

Safety and performance of the Force Argon™ II Argon Enhanced Electrosurgical System were verified through preclinical testing, hardware validation and testing, and software validation.

A. Hardware Validation

The Force Argon™ II Argon Enhanced Electrosurgical System has been tested in accordance with applicable sections of the following standards:

IEC 601-1 (1988), Medical Electrical Equipment Part 1: General Requirements for Safety
IEC 601-2-2 (1991), Medical Electrical Equipment Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment
EN 60601-1-2 (1993) Medical Electrical Equipment, Part 1 General Requirements for Safety, 2, Collateral Standard: Electromagnetic Compatibility- Requirements and Tests
IEC 801-3 (1984), Radiated Electromagnetic Field Requirements
ANSI/AAMI HF18 (1993), Electrosurgical Devices

B. Software Validation

The software for the Force Argon™ II unit has been designed and is being validated in accordance with accepted industry standards.

C. Biocompatibility Testing

The biological safety of the peritoneal pressure tubing has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. The materials have been tested in accordance with USP Class V.

D. Preclinical and Laboratory Bench Testing

Preclinical and laboratory bench testing were performed on the Force Argon™ II Argon Enhanced Electrosurgical System in conjunction with a Valleylab electrosurgical generator and associated accessories using laparoscopic procedures in a swine model and a simulated laparoscopic model, respectively. This testing

showed the Force Argon™ II Argon Enhanced Electrosurgical System functioned according to specification and monitored peritoneal pressure as designed.

IV. Summary of Substantial Equivalence

The Force Argon™ II Argon Enhanced Electrosurgical System is substantially equivalent in function and intended use to the following legally marketed devices:

- Valleylab Force GSU® Argon Enhanced Electrosurgical System.
- Valleylab Force GSU® System with Laparoscopic option.
- Valleylab Force GSU® - SLPM System.

The peritoneal pressure monitoring function of the Force Argon™ II Argon Enhanced Electrosurgical System is comparable to similar systems in currently marketed insufflators.